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CLARENCE EMILE ERIKSEN 3200 SOUTHWEST FREEWAY, SUITE 2355 HOUSTON, TX 77027			FIDEI, DAVID	
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/646,675  
Filing Date: August 22, 2003  
Appellant(s): O'HEERON, PETER T.

**MAILED**  
**JAN 31 2006**  
**Group 3700**

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Clarence E. Eriksen  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed November 25, 2005 appealing from the Office action mailed August 9, 2005.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is incomplete. A correct statement of the status of the claims would include, as follows:

Claims 15-17 are withdrawn from consideration as not directed to the elected invention.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct. It should be noted that the reference to Metcalfe appears to be a minor spelling error, as the patent name listed does not end in an "e". All other aspects of this reference noted by Appellant are correct.

**(8) Evidence Relied Upon**

5,405,328	Vidal et al	4-1995
5,118,297	Johnson	6-1992
5,453,094	Metcalf et al	9-1995

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

In the order contested by Appellant;

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vidal et al (Patent no. 5,405,328). Vidal et al discloses a kit in figures 15 and 16 comprising at least one obturator having what is considered a proximal end 202 where the obturator is grasped, a distal tip defined by any of portions 210-215 and a shaft 201 between the proximal and distal ends. Claim 18 recites the formed as a monolithic structure which is considered a product by process type of limitation of no patentable moment.<sup>1</sup> An orientation indicator is also recited in claim 18 as located near the proximal end, which enables a user to determine by touch the relative position of the tip at the distal end. As shown in figures 15 and 16 of Johnson handle 202 includes an abrupt disc part of larger diameter than shaft 201 adjacent the proximal end. This change in diameter manifestly serves as an orientation indicator to extent claimed where a user can determine by touch the relative position of the tip at the distal end. Hence there is no distinction between Vidal et al and the present invention to the extent claimed.

As to claim 8, members 210-215 define three obturators having blunt, tissue separating and cutting ends.

The rejection is applied in the alternative, as any differences over the claimed invention and Vidal with regard to a monolithic construction or the type of tips used are obvious. Forming the obturator as a monolithic structure is recognized to be within the level of ordinary skill as to make formally separate parts integral would have been obvious in order to obviate the need for assembly and make the use easier. As to the tips used, employing a cutting or tissue-separating tip is dependent upon the particular tools required in the specific procedure. As such these

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<sup>1</sup> A "product by process" claim is directed to the product per se, no matter how actually made, In re Hirao, 190 USPQ 15 at 17(footnote 3). See also In re Brown, 173 USPQ 685; In re Luck, 177 USPQ 523; In re Fessmann, 180 USPQ 324; In re Avery, 186 USPQ 161; In re Wertheim, 191 USPQ 90; and In re Marosi et al, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by process" claim, and the an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it, which is recited in the claim. In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

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parameters are considered to be of no particular criticality but a matter of design choice dependent upon the contents one desires to package in the kit.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (Patent no. 5,118,297) in view of Metcalf et al (Patent no. 5,453,094). Johnson discloses an obturator generally shown as 10 comprising a proximal end 12 where the obturator is grasped, a distal tip 14 and a shaft 18 between the proximal and distal ends. The shaft is formed as a monolithic structure. An orientation indicator is recited in claim 18 as located near the proximal end, which enables a user to determine by touch the relative position of the tip at the distal end. As shown in figures 1 and 2 of Johnson a washer 22 is disclosed as received adjacent the handle or proximal end. This washer has a wider diameter than shaft 18, particularly at the distal end 14, and manifestly serves as an orientation indicator to extent claimed. Where a user can determine by touch the relative position of the tip at the distal end.

The difference between the claimed subject matter and Johnson resides in a case for enclosing the at least one obturator. Metcalf et al figures 2-9 disclose that it is notoriously well known to place instrument in cases of individual packages. It would have been obvious to one skilled in the art to provide the at least one obturator of Johnson with a case for enclosing the same as taught by Metcalf, in order to provide a package for shipment and handling of the obturator.

In order to distinguish over the prior art there must be some functional relationship between the specific content of the printed matter to the apparatus employing the printed matter, i.e., the printed matter depends on the apparatus, and the apparatus depends on the printed matter

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Although factually distinct, the *In re Ngai*, 70 USPQ2d 1862 (Fed. Cir. 2004) and *In re Gulack*, 217 USPQ 410 (Fed. Cir. 1983), held the same basic premise of “where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.

In the present case Johnson discloses what is shown as printed mater in figure 1 on the handle 12 in order to provide information to the use for identifying a particular sized obturator, see col. 3, lines 53-37. The presently claimed obturator decorated with graphical and/or textual information has no functionally distinguishing relationship over Johnson in that the indicia aids one in identifying a particular sized obturator. As to claim 9, the specific indicium used to “decorate” the obturator relates to printed matter and is of no patentable significance.

## **10) Response to Argument**

### ***A. Standard for Establishing Anticipation***

The Examiner realizes it is a fundamental tenet of patent law that the standard for anticipation is one of strict identity. To anticipate a claim for a patent, a single prior art reference must contain all of the elements recited in the claim.

"An anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice or device." *In re Donohue*, 766 F.2d 531, 266 USPQ 619, 621 (Fed. Cir. 1985).

"Exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference." *Atlas Powder Company v. E.I. du Pont De Numours*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984).

However, it should also be noted the law of anticipation does not require that the reference teach what applicant has disclosed, but only that the claims "read on" something disclosed in the reference. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 281 USPQ 871 (Fed. Cir. 1983). Furthermore, it is only necessary that the reference include structure capable of performing the recited function in order to meet the functional limitations of the claim as a

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reference must disclose the claimed subject matter expressly or inherently, *Constant v. Advanced Microwave Devices, Inc.*, 7 USPQ2d 1057 (Fed. Cir. 1989). This is believed to be fundamental tenets of anticipation where the Examiner and Appellant disagree regarding the specific facts surround the present appeal.

***B. Standard With Respect to Establishing a Prima Facie Case of Obviousness***

The Examiner takes no issue with the steps set forth by Appellant in order to establish a prima facie case of obviousness. The same is explicitly set forth in § M.P.E.P. 2143.01-03. It has been long established that there must be some suggestion or motivation for combining references in order to establish obvious under 35 U.S.C. 103(a). Even if based on a single reference modification, see pages 6 and 7 of the brief.

In so far as modifying a prior art device that would change the principle of operation or require substantial reconstruction (pages 7 and 8 of brief), it appears any such consideration would be a fact specific review. All determinations of patentability under 35 U.S.C. 103(a) involves a modification some type. Whether a principle change in operation, guided by any such modification results in the device being incapable of achieving its' intended purpose, is the issue to be resolved in showing the changes are not suggested or not, see *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Regarding "casting" one back into the mind of "one of ordinary skill in the art" at the time the invention was made, it is believed nothing presented herein runs counterintuitive to this methodology. All the references cited represent relevant teachings and pertinent concepts that would have been well recognized by the hypothetical person of ordinary skill in this art.

Each reference cited as evidence that the presently claimed subject matter fails to represent anything novel or unobvious is no less than eight years prior to the present filing date. Hence, the principles relied upon from these prior art documents represent characteristics well established to



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those skilled in this art. Indeed, close adherence to the teachings of these references where nothing from Appellant's disclosure is relied upon to establish the proposed rejection *prima facie* establishes a failure to be affected by the insidious effects of hindsight reasoning.

### **C. The Rejections of Claim 18 under § 102 and § 103 Are not Erroneous**

1. A factual finding can be said to be clearly erroneous "when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed", e.g., compare *Pennwalt Corp. v. Durand-Wayland, Inc.* 833 F.2d 931, 934 4 USPQ2d 1737, 1739 (Fed. Cir. 1987, in banc, quoting from *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 76 USPQ 430, 443 (1948)). Appellant has failed to establish a substantial body of evidence demonstrating that the Examiner's holding of claim 18 as being unpatentable over Vidal is erroneous.

Appellant takes issue with the Examiner's findings that the shaft 201 towards a proximal end that transitions into handle 202 in figure 16 represents a change in diameter defining an orientation indicator in as much as is claimed and disclosed. Arguing that, significantly, nothing in Vidal describes this change in diameter being any sort of indicator. Yet Appellant also argues by sharp contrast one can touch the indicator 20 of the present invention and know the orientation of the obturator. And what is the "indicator" disclosed by the present invention that provides in sharp contrast to Vidal? One or more raised surfaces, see page 6, paragraph [17] of the present disclosure. Exactly what Vidal figure 16 shows. The obturator is far from uniform in construction with an equal diameter from one end to the other. Where the shaft 201 meets handle 202, there is a sharp distinction in shape where a raised surface is defined over the rest of the device. Defining a raised surface at the proximal end that manifestly is capable of functioning as an orientation indicator, which enables a user to determine by touch the relative position of the tip at the distal end. Appellant brief provides nothing demonstrating otherwise.

With regard to claim 18 being amended to include "the proximal end and distal ends and the shaft being formed as a monolithic structure" in order to avoid Vidal (see the paper filed

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3/25/05), Appellant argues that the “Examiner no doubt recognized that Vidal did not disclose a monolithic structure and avoided addressing that fact by arbitrarily deciding that the limitation “monolithic” in claim 18 does not exist”, page 10 first line of the third paragraph. It is requested Appellant’s ad hominem remarks be dismissed with prejudice. This is degradation of the Examiner’s competency and to assert this allegation where the Examiner has demonstration due diligence in treating all the limitations of the claims is unconscionable.

First and foremost it is noted claim recites the device “being formed” as a monolithic structure. Dictionary.com defined “formed” as; to mold or shape into a particular form, to arrange, give form to or fashion. The plain, ordinary meaning of “formed” as used herein gives rise to a manner in which something is done.

From the ordinary meaning of the terms, a device “being formed” imparts a manner in which a series of operations, actions, functions or steps proceeds. This is tantamount to a process limitation in a product claim and nothing in Appellant’s remarks suggest otherwise. “The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process”, see § M.P.E.P. 2113.

Dictionary.com also defines monolithic as;

- ☐ Constituting a monolith: *a monolithic sculpture.*
- ☐ Massive, solid, and uniform: *the monolithic proportions of Stalinist architecture.*
- ☐ Constituting or acting as a single, often rigid, uniform whole: *monolithic worldwide movement.*

Even when the pieces of Vidal are assembled into any one of the three obturators possible from the package of figure 16, “the proximal end and distal ends and the shaft being formed as a monolithic structure” imparts no structural distinction, no different operation mode of the obturator or other physical characteristic that would serve to distinguish the claimed invention over Vidal on this basis.

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For these and the above reasons it is respectfully submitted the rejection under 35 U.S.C. 102(b) be affirmed.

2. With regard to the prima facie case of obviousness, it is not seen where this is relevant to the orientation indicator. The aforementioned rejection is applied in the alternative, as any differences over the claimed invention and Vidal with regard to a monolithic construction, or the type of tips, used would have been obvious. Forming the obturator as a monolithic structure is recognized to be within the level of ordinary skill as to make formally separate parts integral would have been obvious in order to obviate the need for assembly and make the use easier.

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), see M.P.E.P. §2144.

*"In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965) (A claim to a fluid transporting vehicle was rejected as obvious over a prior art reference which differed from the prior art in claiming a brake drum integral with a clamping means, whereas the brake disc and clamp of the prior art comprise several parts rigidly secured together as a single unit. The court affirmed the rejection holding, among other reasons, "that the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice.")", see M.P.E.P. §2144.04 IV (B). This clearly provides a motivation showing that suggests the modification along with the reasons set forth in the rejection.

#### **D. The § 103 Rejection of Claim 18 Based on Johnson in View of Metcalf**

1. Appellant argues several differences exist between the claims and Johnson that fail to establish prima facie obviousness. First is it said Johnson fails to disclose an obturator for use in endoscopic surgery.

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However, as reiterated from the Final Rejection, the recitation of the obturator for use in endoscopic surgery is of no patentable moment. In order to further limit the claim there must be some distinction based upon the intended use recited. "However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art, see M.P.E.P. § 2111.02 THE INTENDED USE MAY FURTHER LIMIT THE CLAIM IF IT DOES MORE THAN MERELY STATE PURPOSE OR INTENDED USE. The examiner can see no structural differences between the claimed invention and the prior art of Johnson based upon the intended use recited.

As to the tip of Johnson being "used either to cut or separate the tissue of a patient", it is not agreed it is impossible to use the tip of Johnson to cut or separate tissue. As shown in figure 5, the tip is used in the canal of the tooth to separate tissue, compare the left and right apices 30 of figure 5. Also the tip is used to apply filler material 26 where the tissue is separated. Accordingly, there is nothing in the claimed limitations that are not disclosed by Johnson in this regard that would obviate the prima facie holding.

In a similar fashion as with Vidal, the washer 22 in figure 2 presents a sharp distinction in shape where a raised surface is defined over the rest of the device. Defining a raised surface at the proximal end that manifestly is capable of functioning as an orientation indicator, which enables a user to determine by touch the relative position of the tip at the distal end. Appellants brief provides nothing demonstrating otherwise. With regard to no hand fitting within a human tooth, this is only when the obturator is loaded with a filler material for application as shown in figure 5. Which is not the case in figure 2.

As to the relative size of the obturator, Johnson mentions nothing regarding sizes nor does Appellant demonstrate human touch perception limits. For as much as Johnson discloses root canal can be performed on large mammals, as in veterinary practice. Finally, the Examiner points out the home keys (J & F) on the keyboard used to type this document have a small projection distinguishing these keys from all the other keys. This enables location of the index fingers on the home keys. Yet one is to reason the washer of a root canal obturator is imperceptible to

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human touch because the length is almost three times the size of the exposed tooth. Clearly this is at odds with what the Johnson intuitively discloses. Particularly when considering the obturator is handled to apply the filler material 26 prior to insertion into the tooth. In view of the forgoing, it is submitted the washer 22 of Johnson is *prima facie* capable of functioning as an orientation indicator in as much as is disclosed and claimed.

2. The Examiner takes no issue with Appellant proposal that any use of the device of Johnson as an obturator for endoscopic surgery requires substantial reconstruction and redesign. However, nowhere is this what the rejection proposes. It is well settled that intended use cannot be used to set apart structural features on that basis alone. A statement of intended use, which is merely recited in the preamble does not limit the recitations of structure, which follow the preamble to the indicated use. In *re* Tuominen, 671 F.2d 1359 (C.C.P.A. 1982). A statement of intended use does not qualify or distinguish the structure claimed over the prior art. In *re* Sinex, 309 F.2d 488 (C.C.P.A. 1962). Accordingly, Appellant's arguments in this regard are not well founded.

3. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present instance, Appellant has not demonstrated what was derived from their disclosure to establish the proposed rejection. Accordingly, it is submitted there is no reasonable basis for such a claim.

**E. Dependent Claims 8 and 9 stand or fall with the above rejections.**

While it is well established that the dependent claims are patentable if the claims from which they depend are patentable, the opposite would also be true herein.

The failure to address specific distinctions is a concession by the applicant that, if the ground of rejection were sustained as to any one of the rejected claims, it will be equally applicable to all of

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them. This is consistent with the practice of the Court of Appeals for the Federal Circuit indicated in such cases as *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991); *In re Nielson*, 816 F.2d 1567, 2 USPQ2d 1525 (Fed. Cir. 1987); *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); and *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

Accordingly, it is submitted claims 8 and 9 fail to define patentable subject matter.

### SUMMARY

As contemplated herein, Appellant's claimed invention fails to adequately differentiate the intellectual property rights of the present invention over that established in the prior art. A simple obturator having an orientation indicator located near a proximal end is sufficiently anticipated by Vidal in as much as is claimed and disclosed. The obturator being formed as a monolithic construction is not of sufficient description to be considered novel. Even if a monolithic structure were shown to provide a distinction over the obturator of Vidal, it would have been well within the level of ordinary skill to form a monolithic obturator for the aforementioned reasons. —

With regard to the rejection based on Johnson in view of Metcalf, it is believed a strong case of prima facie obviousness exists. To place medical instruments in a case for storage, transportation or to maintain a sterile environment is widely accepted. This is the sole difference between claims 18 and Johnson. Metcalf et al figures 2-9 disclose that it is notoriously well known to place instrument in cases of individual packages. Placing the obturator of Johnson in a case for enclosing the device is fairly taught by Metcalf and would not have involved an invention.

### **(11) Related Proceeding(s) Appendix**


No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

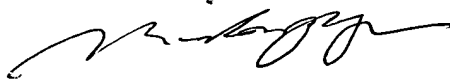
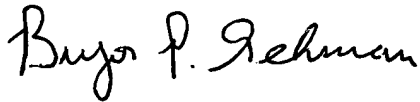
Respectfully submitted,

dtf



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